

Title 19 - DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30 - Division of Regulation and Licensure
Chapter 40 – Comprehensive Emergency Medical Services Systems Regulations

PROPOSED REGULATIONS (February 26, 2010)

19 CSR 30-40. XXX Standards for STEMI Center Designation

PURPOSE: This rule establishes standards for Level I, II, III and IV STEMI center designation.

EDITOR'S NOTE:

*I-R, II-R, III-R, or IV-R after a standard indicates a requirement for Level I, II, III, or IV STEMI center respectively.
I-IH, II-IH, III-IH, or IV-IH after a standard indicates an in-house requirement for Level I, II or III STEMI center respectively.*

I-IA, II-IA, III-IA, or IV-IA indicates an immediately available requirement for Level I, II, III, or IV STEMI center respectively.

I-PA, II-PA, III-PA, or IV-PA indicates a promptly available requirement for Level I, II, III, or IV STEMI center respectively.

PUBLISHER'S NOTE: The Secretary of State has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome and expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) General Standards for STEMI Center Designation

- (A) The hospital board of directors, administration, medical staff and nursing staff shall demonstrate a commitment to quality STEMI care. Methods of demonstrating the commitment shall include, but not be limited to, a board resolution that the hospital governing body agrees to establish policy and procedures for the maintenance of services essential for a STEMI center; assure that all STEMI patients will receive medical care at the level of the hospital's designation; commit the institution's financial, human and physical resources as needed for the STEMI program; and establish a priority admission for the STEMI patient to the full services of the institution. (I-R, II-R, III-R, IV-R)
- (B) STEMI centers shall agree to accept all STEMI patients appropriate for the level of care provided at the hospital, regardless of race, sex, creed or ability to pay. (I-R, II-R, III-R, IV-R)
- (C) The hospital shall demonstrate evidence of a **STEMI program**. The STEMI program shall be available twenty-four (24) hours a day, seven (7) days a week to treat and evaluate STEMI patients and meet the following requirements:
 - 1. Maintain a **STEMI team** that at a minimum consists of; (I-R, II-R, III-R, IV-R)
 - A. A core team to provide administrative oversight;
 - (I) A physician experienced in diagnosing and treating cardiovascular disease and STEMI, usually the STEMI medical director; and
 - (II) At least one other health care professional or qualified individual credentialed in STEMI care as determined by the hospital, usually the STEMI program manager/coordinator;
 - 2. A **clinical team** appropriate to the center level designation that may include but not be limited to cardiologists, interventional cardiologists, cardiovascular surgeons, anesthesiologists, emergency department physicians, intensivists and other STEMI center clinical staff when applicable.
 - 3. The STEMI team has appropriate experience to **maintain skill and proficiency** to care for STEMI patients. The hospital shall maintain evidence of this by documenting the following:
 - A. STEMI team members meet position qualifications and continuing education requirements as outlined in these regulations and by the hospital; (I-R, II-R, III-R, IV-R)

- B. The core team and members of the STEMI call roster shall participate in at least half of the regular, ongoing STEMI program peer review meetings as shown in meeting attendance documents; (I-R, II-R, III-R, IV-R)
- C. STEMI team members or liaisons shall participate in at least half of the regular ongoing STEMI program performance improvement and patient safety meetings as shown in minutes and meeting attendance documents. The STEMI medical director shall ensure and document dissemination of information and findings from the performance improvement and patient safety meetings to the STEMI team members; (I-R, II-R, III-R, IV-R)
- D. STEMI team members document continued experience in management of sufficient numbers of STEMI patients to maintain skill levels as defined by the hospital, STEMI medical director, and these regulations; (I-R, II-R, III-R, IV-R)
- E. Core team members of the STEMI call roster in Level I and Level II STEMI centers shall document a minimum of ten (10) hours every year of continuing education in acute coronary syndrome. All other member of the STEMI call roster shall document a minimum of ten (10) hours every year of continuing education in cardiovascular disease as determined appropriate by the STEMI center medical director and as appropriate to the practitioner's level of responsibility; (I-R, II-R)
- F. All members of the STEMI call roster in Level III and Level IV STEMI centers shall document a minimum of eight (8) hours every other year of continuing education in cardiovascular disease as determined appropriate by the STEMI center medical director and as appropriate to the practitioner's level of responsibility; and (III-R, IV-R)
- G. STEMI team members review regional outcome data on quality of patient care as part of the performance improvement and patient safety process. (I-R, II-R, III-R, IV-R)
- 4. Maintain a **multidisciplinary team**, in addition to the STEMI team to support the care of STEMI patients; (I-R, II-R, III-R, IV-R)
 - A. The multidisciplinary team shall include an appropriate representative from hospital units as appropriate for care of each STEMI patient. The units represented on the multidisciplinary team may include but not be limited to: administration, emergency medical services, intensive care unit, cardiac catheterization lab, pharmacy, laboratory, cardiac unit, cardiac rehabilitation and discharge planning;
 - B. The multidisciplinary team members or representatives shall attend at least half of the STEMI program performance improvement and patient safety meetings which shall be documented in meeting minutes and attendance lists.
- (D) The hospital shall **provide the services of cardiac catheterization laboratory staffed by a cardiac catheterization team** that shall be available twenty-four (24) hours a day, seven (7) days a week and consist of, but not be limited to: (I-R/PA, II-R/PA)
 - 1. An interventional cardiologist(s). The hospital credentialing committee shall document that the interventional cardiologists have completed appropriate training and conducted sufficient coronary interventional procedures to obtain the necessary competence. In addition, the interventional cardiologists shall conduct a sufficient number of Percutaneous Coronary Interventions (PCIs) on an annual basis to maintain that competence. It is recommended that interventional cardiologist(s) perform seventy-five (75) or more elective PCIs per physician per year and eleven (11) or more primary PCIs per physician per year;
 - 2. Other health care professionals as deemed necessary.

- (E) To be designated a **Level I** STEMI Center, a hospital shall meet the following criteria:
1. The cardiac catheterization laboratory shall perform: (I-R):
 - A. At least an average of four hundred (400) or more elective Percutaneous Coronary Interventions (PCIs) per year over three (3) years per center, and
 - B. At least an average of forty nine (49) or more primary PCIs per year over three (3) years per center; and
 2. Be able to provide on-site emergency cardiothoracic surgical services when needed twenty-four (24) hours a day, seven (7) days a week. (I-R/PA)
- (F) To be designated a **Level II** STEMI Center, a hospital shall meet the following criteria: (II-R, PA)
1. The cardiac catheterization laboratory shall perform:
 - A. An average of two hundred (200) or more elective PCIs per year over three (3) years per center, and
 - B. An average of thirty six (36) or more Primary PCIs per year over three (3) years per center; and
 2. Be able to provide on-site emergency cardiothoracic surgical services or have a proven plan, transfer agreement and expedited transfer process for cardiothoracic surgery back-up in a nearby hospital with appropriate hemodynamic support capability for transfer. The plan shall ensure that once the decision is made to perform surgery, the STEMI patient is in the operating room of the receiving hospital within sixty (60) minutes.
 3. A hospital that performs less than two hundred (200) elective PCIs or less than thirty-six (36) primary PCIs per year shall meet the following standards to qualify for a Level II center designation:
 - A. If an institution performs less than an annual average of thirty-six (36) primary PCIs over three (3) years, it shall perform an annual average of two hundred (200) or more elective PCIs over three (3) years and all operators shall perform seventy-five (75) or more elective PCIs and eleven (11) or more primary PCIs per year. If an operator does not perform eleven (11) or more primary PCIs per year, he or she shall have a defined mentoring relationship with a highly experienced operator until determined competent to perform primary PCIs by the mentor and facility; or
 - B. If an institution performs less than an annual average of two hundred (200) elective PCIs over three (3) years, it shall perform an annual average of thirty-six (36) primary PCIs over three (3) years and all operators shall perform seventy-five (75) or more elective PCIs and eleven (11) or more primary PCIs per year or have a defined mentoring relationship with a highly experienced operator until determined competent to perform primary PCI by the mentor and facility; and
 - C. Be able to provide on-site emergency cardiothoracic surgical services or have a proven plan, transfer agreement and expedited transfer process for cardiothoracic surgery back-up in a nearby hospital with appropriate hemodynamic support capability for transfer. The plan shall ensure that once the decision is made to perform surgery, the STEMI patient is in the operating room of the receiving hospital within sixty (60) minutes;
 - D. Cardiac intensive care capability;
 - E. Evidence of a proven plan, transfer agreement and expedited transfer process to higher level care in a nearby hospital with appropriate hemodynamic support capability for transfer;
 - F. Medical contact to balloon or door to balloon (D2B) times;
 - (I) Ninety (90) minutes or less hospital door to balloon (D2B) seventy-five percent (75%) of the time, and
 - (II) Submission of first medical contact to balloon times to the department;
 - G. The center and its operators have historical and current risk-adjusted outcome and process measures that are comparable to those in national registries or the state registry when sufficient data has been collected as determined by the department.

- (G) To be designated a **Level III or Level IV** center, a hospital will meet all of the STEMI program requirements included in subsection (C) and other requirements as specified in these regulations. (III-R, IV-R)
- (H) The hospital shall appoint a physician to serve as the **STEMI medical director** who meets the following requirements;
1. The STEMI medical director shall be a board-certified or board-admissible interventional cardiologist or cardiologist at a Level I and Level II centers; (I-R, II-R)
 - A. Those interventional cardiologists or cardiologists in the medical director position at the time the regulations take effect or hired within six (6) months of the effective date of these regulations who are not board-certified or admissible shall be able to continue in this position;
 - B. All new STEMI medical directors appointed by the hospital effective six (6) months after these regulations take effect shall be a board-certified or admissible interventional cardiologists or cardiologists;
 2. A board-certified or board-admissible physician shall serve as STEMI medical director at a Level III and Level IV center; (III-R, IV-R)
 - A. Those physicians in the medical director position at the time the regulation take effect or hired within six (6) months of the effective date of these regulations who are not board-certified or admissible shall be able to continue in this position;
 - B. All new STEMI medical directors appointed by the hospital effective six (6) months after these regulations take effect shall be a board-certified or board-admissible physician;
 3. There shall be a job description and organization chart depicting the relationship between the STEMI medical director and other services; (I-R, II-R, III-R, IV-R)
 4. It is recommended that the STEMI medical director is a member of the catheterization lab team call roster; (I-R, II-R)
 5. The STEMI medical director shall be responsible for the oversight of the education and training of the medical and clinical staff in STEMI care; (I-R, II-R, III-R, IV-R)
 6. The STEMI medical director shall document a minimum average of ten (10) hours every year of continuing medical education (CME) in acute coronary syndrome; (I-R, II-R)
 7. The STEMI medical director shall document a minimum average of eight (8) hours every other year of continuing medical education (CME) in cardiovascular disease; (III-R, IV-R)
 8. The STEMI medical director shall participate in the STEMI center's research and publication projects. (I-R)
- (I) There shall be a **STEMI program coordinator/manager** who is a registered nurse, other clinical staff or qualified individual; (I-R, II-R, III-R, IV-R)
1. There shall be a job description and organization chart depicting the relationship between the STEMI program coordinator/manager and other services; (I-R, II-R, III-R, IV-R)
 2. The STEMI program coordinator/manager shall document a minimum average of ten (10) hours every year of continuing education in cardiovascular disease as determined appropriate by the STEMI center medical director and as appropriate to the practitioner's level of responsibility and attend one (1) national, regional or state meeting every other year on cardiovascular disease. If the national, regional or state meeting provides continuing education hours, those hours may count toward the yearly requirement; (I-R)
 3. The STEMI program coordinator/manager shall document a minimum average of eight (8) hours every year of continuing education in cardiovascular disease as determined appropriate by the STEMI center medical director and as appropriate to the practitioner's level of responsibility and attend one national, regional or state meeting every three (3) years on cardiovascular disease. If the

- national, regional or state meeting provides continuing education hours, those hours may count toward the yearly requirement; (II-R)
4. The STEMI program coordinator/manager shall document a minimum average of eight (8) hours every other year of continuing education in cardiovascular disease as determined appropriate by the STEMI center medical director and as appropriate to the practitioner's level of responsibility; (III-R, IV-R)
 5. The STEMI program coordinator/manager shall participate in the formal quality improvement program. (I-R, II-R, III-R, IV-R)
- (J) There shall be a specific and well-organized system for the emergency department to rapidly notify and activate the STEMI team or STEMI/cardiac catheterization lab team, as appropriate for center level designation, at the time of Emergency Department STEMI identification or verification of EMS STEMI identification. (I-R, II-R, III-R, IV-R)
- (K) The hospital shall have a protocol regarding "One call cardiac catheterization lab activation by EMS" at time of EMS STEMI identification as appropriate to the hospital's process. (I-R, II-R)
- (L) The hospital shall have a one-call STEMI team or STEMI/cardiac catheterization lab team activation protocol as appropriate for center level designation that establishes the following: (I-R, II-R, III-R, IV-R)
1. The criteria used to triage STEMI patients;
 2. The person authorized to notify STEMI team or STEMI team/cardiac catheterization lab team members when a suspected STEMI patient is en route or has arrived at the STEMI center;
 3. The method for immediate notification and response requirements for STEMI team or STEMI/cardiac catheterization lab team members when a suspected STEMI patient is en route to the STEMI center; and
 4. All members of the STEMI team or STEMI/cardiac catheterization lab team call roster shall comply with the availability and response requirements per the hospital policy. If not on the hospital premises, STEMI/cardiac catheterization lab team members who are on call shall carry electronic communication devices at all times to permit contact by the hospital and shall be promptly available.
- (M) STEMI centers shall have a call roster providing twenty-four (24) hours a day, seven (7) days a week cardiology coverage or regional networking agreement with a Level I or Level II STEMI center for telephone consult available within fifteen (15) minutes of notification of patient when a cardiologist is not available on site. (I-R, II-R, III-R, IV-R)
- (N) STEMI centers shall have transfer agreements between referring and receiving facilities;
1. The hospital shall have a one-call transfer protocol to a Level I or Level II designated STEMI center that establishes the criteria used to triage STEMI patients and identifies the persons authorized to notify the designated STEMI center; and (II-R, III-R, IV-R)
 2. The hospital shall have a rapid transfer process in place to transport a STEMI patient to a higher level of STEMI care when needed. (II-R, III-R, IV-R)
- (O) There shall be a lighted designated helicopter landing area to accommodate incoming medical helicopters; (I-R, II-R, III-R, IV-R)
1. The landing area shall serve as the receiving and take-off area for medical helicopters and shall be cordoned off from the general public when in use to assure its continual availability and safe operation; and (I-R, II-R, III-R, IV-R)
 2. It is recommended the landing area shall be no more than three (3) minutes from the emergency department. (I-R, II-R, III-R, IV-R)

- (P) Cardiac rehabilitation services shall be directed by a physician (e.g., cardiologist or physician experienced in cardiac rehabilitation). (I-R, II-R)
- (Q) The hospital shall demonstrate that there is a plan for adequate post-discharge follow-up on STEMI patients, including cardiac rehabilitation and repatriation if indicated. (I-R, II-R, III-R, IV-R)
- (R) Data on each STEMI patient who is admitted to the hospital, transferred out of facility, or dies resulting from the STEMI (independent of hospital admission or hospital transfer status) shall be entered into the Missouri STEMI registry and shall meet the following criteria; (I-R, II-R, III-R, IV-R)
 - 1. Includes at least one (1) code within the range of the following diagnostic codes as defined in the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9)-(CM) 410.0-410.6 and 410.8 which is incorporated by reference in this rule as published by the Centers for Disease Control and Prevention in 2006 and is available at National Center for Health Statistics, 1600 Clifton Road, Atlanta, Georgia 30333. This rule does not incorporate any subsequent amendments or additions and must include one of the following criteria;
 - 2. The registry data shall be submitted electronically in a format defined by the department. Electronic data shall be submitted quarterly, within ninety (90) days after the quarter ends. The STEMI registry must be current and complete; and
 - 3. Information provided by hospitals on the STEMI registry shall be subject to the same confidentiality requirements and procedures contained in section 192.067, RSMo.
- (S) A hospital diversion protocol must be maintained in accordance with state regulations. This protocol is designed to allow best resource management within a given area. This protocol must contain a defined performance improvement and patient safety process to review and validate established criteria within that institution. Hospital diversion information must be maintained to include date, length of time and reason for diversion. (I-R, II-R, III-R, IV-R)

(2) Medical Staffing Standards for STEMI Center Designation

- (A) There shall be a delineation of privileges for the cardiologists, cardiothoracic surgeons, and interventional cardiologists made by the medical staff credentialing committee. (I-R, II-R, III-R)
- (B) Physicians who are credentialed by the hospital for STEMI care shall be available as indicated. This includes the following:
 - 1. Cardiology; (I-R/PA, II-R/PA)
 - 2. Interventional Cardiologist; (I-R/PA, II-R/PA)
 - 3. Cardiothoracic surgery:
 - A. Cardiothoracic surgeon and back-up coverage; (I-R/PA, II-R/PA—for those STEMI II centers that provide cardiothoracic surgery)
 - B. Cardiothoracic surgeon and back-up coverage arrangements with STEMI center I or II that provides surgery; (II-R for those STEMI II centers that do not provide cardiothoracic surgery to ensure that the STEMI patient is in the operating room of the receiving STEMI center within sixty (60) minutes of the time surgery is determined needed)
 - 4. Emergency department physician; (I-R/IH, II-R/IH, III-R/IH, IV/IA)
 - 5. Internal medicine; (I-R/PA, II-R/PA, III-R/PA)
 - 6. Diagnostic radiology; and (I-R/IA, II-R/IA, III-R/IA, IV/PA)
 - 7. Anesthesiology; (I-PA, II-PA)
 - A. Anesthesiology staffing requirements may be fulfilled by anesthesiology residents or certified registered nurse anesthetists (CRNA), or anesthesia assistants capable of assessing emergent situations in STEMI patients and of providing any indicated treatment including induction of

anesthesia. When anesthesiology residents, anesthesia assistants or CRNA's are used to fulfill availability requirements, the staff anesthesiologist on call will be advised and promptly available and present for all operative interventions and emergency airway conditions. The CRNA may proceed with life preserving therapy while the anesthesiologist is en route under the direction of the cardiologist/cardiovascular surgeon, including induction of anesthesia.

(3) Standards for Hospital Resources and Capabilities for STEMI Center Designation

- (A) The hospital shall meet emergency department standards for STEMI center designation, as follows:
1. The emergency department staffing shall ensure immediate triage and appropriate care of the STEMI patient; (I-R, II-R, III-R, IV-R)
 - A. The medical director of the emergency department shall be board-certified or board-admissible in emergency medicine; (I-R, II-R)
 - (I) Those emergency medicine physicians in the medical director position at the time the regulations take effect or hired within six (6) months of the effective date of these regulations who are not board-certified or admissible shall be able to continue in this position;
 - (II) All new medical directors appointed by the hospital effective six (6) months after these regulations take effect shall be board-certified or admissible in emergency medicine;
 - B. The medical director of the emergency department shall be a board-certified or board-admissible physician; (III-R, IV-R)
 - (I) Those physicians in the medical director position at the time the regulations take effect or hired within six (6) months of the effective date of these regulations who are not board-certified or admissible shall be able to continue in this position;
 - (II) All new medical directors appointed by the hospital effective six (6) months after these regulations take effect shall be board-certified or admissible physician;
 - C. There shall be an emergency department physician competent in STEMI care covering the emergency department twenty-four (24) hours a day, seven (7) days a week; (I-R/IH; II-R/IH; III-R/IH; IV-R/IA)
 - D. The emergency department physician that provides coverage shall be current in cardiovascular care and each physician: (I-R, II-R, III-R, IV-R)
 - (I) Shall document a minimum average of four (4) hours every year of CME in cardiovascular disease; (I-R, II-R)
 - (II) Shall document a minimum average of six (6) hours every other year of CME in cardiovascular disease; (III-R, IV-R)
 - E. There shall be written policy defining the organizational relationship of the emergency department physicians to other physician members of the STEMI team; (I-R, II-R)
 - F. All registered nurses assigned to the emergency department shall be determined to be credentialed in the care of the STEMI patient by the hospital within one (1) year of assignment; (I-R, II-R, III-R, IV-R)
 - (I) Registered nurses shall document a minimum of four (4) hours every year of cardiovascular disease continuing nursing education; (I-R, II-R)
 - (II) Registered nurses shall document a minimum of six (6) hours every other year of cardiovascular disease continuing nursing education; (III-R, IV-R)
 - (III) Registered nurses shall maintain core competencies in the care of the STEMI patient yearly as determined by the hospital; (I-R, II-R, III-R, IV-R)

- G. The emergency department shall have written care protocols for identification, triage and treatment of acute STEMI patients available to emergency department personnel and should be reviewed annually and revised as needed; and (I-R, II-R, III-R, IV-R)
- H. The emergency department shall maintain a fibrinolysis pathway when PCI is not achievable within the designated time frame and fibrinolysis is achievable within the designated time frame. (I-R, II-R, III-R, IV-R)
- 2. The emergency department shall have the following **equipment** for resuscitation and life support available:
 - A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes, bag-mask resuscitator, sources of oxygen and mechanical ventilator; (I-R, II-R, III-R, IV-R—except mechanical ventilator not required at Level IV)
 - B. Suction devices; (I-R, II-R, III-R, IV-R)
 - C. Electrocardiograph, cardiac monitor and defibrillator; (I-R, II-R, III-R, IV-R)
 - D. Central line insertion equipment; (I-R, II-R, III-R)
 - E. All standard intravenous fluids and administration devices including intravenous catheters and intraosseous; (I-R, II-R, III-R, IV-R)
 - F. Drugs and supplies necessary for STEMI emergency care; (I-R, II-R, III-R, IV-R)
 - G. Two-way communication link with emergency medical service (EMS) vehicles; (I-R, II-R, III-R, IV-R)
 - H. Equipment necessary to communicate with EMS regarding pre-hospital ECG findings; (I-R, II-R, III-R, IV-R)
 - I. End-tidal carbon dioxide monitor; (I-R, II-R, III-R, IV-R)
 - J. Temperature control devices for patient and resuscitation fluids; (I-R, II-R, III-R, IV-R)
 - K. External pacemaker; and (I-R, II-R, III-R, IV-R)
 - L. Transvenous pacemaker; (I-R/IA, II-R/IA, III-R/IA)
- 3. There shall be documentation that all equipment is checked according to the hospital preventive maintenance schedule. (I-R, II-R, III-R, IV-R)
- (B) The hospital shall have a designated **intensive care unit** (ICU) for STEMI center designation; (I-R, II-R)
 - 1. The intensive care unit shall ensure **staffing** to provide appropriate care of the STEMI patient; (I-R, II-R)
 - A. There shall be a designated medical director for the ICU who has twenty-four (24) hours a day, seven (7) days a week access to a physician knowledgeable in STEMI who meets the continuing education requirements in these regulations;
 - B. A physician who is not the emergency department physician shall be on duty in the ICU or available twenty-four (24) hours a day, seven (7) days a week in the STEMI center;
 - C. The registered nurse/patient ratio used shall be one to one (1:1) or one to two (1:2);
 - D. Registered nurses shall have a minimum of eight (8) hours every year of cardiovascular continuing nursing education as determined appropriate by the STEMI center medical director and as appropriate to the practitioner's level of responsibility;
 - E. Registered nurses shall maintain core competencies in the care of the STEMI patient yearly as determined by the hospital;
 - 2. There shall be beds for STEMI patients or comparable level of care provided until space is available in ICU; (I-R, II-R)
 - 3. The ICU shall have written care protocols for identification and treatment of acute STEMI patients available to ICU personnel and be reviewed annually and revised as needed; (I-R, II-R)

4. **Equipment** for resuscitation and to provide life support for the STEMI patient shall be available for the intensive care unit. This equipment shall include, but not be limited to: (I-R, II-R)
 - A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes, bag-mask resuscitator, and a mechanical ventilator;
 - B. Oxygen source with concentration controls;
 - C. Cardiac emergency cart, including medications;
 - (I) External pacemaker;
 - (II) Transvenous pacemaker;
 - D. Telemetry, electrocardiograph, cardiac monitor and defibrillator;
 - E. Electronic pressure monitoring and pulse oximetry;
 - F. End-tidal carbon dioxide monitor;
 - G. Patient weighing devices; and
 - H. Drugs, intravenous fluids and supplies;
5. There shall be documentation that all equipment is checked according to the hospital preventive maintenance schedule. (I-R, II-R)
- (C) **Cardiac catheterization lab** capabilities for STEMI center designation shall include: (I-R, II-R)
 1. Angiography with interventional capability available twenty-four (24) hours a day, seven (7) days a week; (I-R/PA, II-R/PA)
 2. Registered nurses and clinical staff shall document a minimum of eight (8) hours of acute coronary syndrome-related continuing education per year;
 3. All members of the catheterization lab and team shall maintain core competencies yearly as determined by the hospital;
 4. Resuscitation equipment shall be readily available in the catheterization lab;
 5. The following diagnostic equipment shall be available: (I-R, II-R)
 - A. Sheaths;
 - B. Diagnostic wires;
 - C. Diagnostic catheters;
 - D. Manifold or contrast injector/delivery system; and
 - E. Pressure tubing.
 6. The following interventional equipment shall be available:
 - A. Sheaths; (I-R, II-R)
 - B. Interventional guide wires; (I-R, II-R)
 - C. Interventional guide catheters; (I-R, II-R)
 - D. Balloon catheters; (I-R, II-R)
 - (I) Compliant;
 - (II) Non-compliant;
 - E. Stents; (I-R, II-R)
 - (I) Bare metal stents;
 - (II) Drug eluting stents;
 - F. Balloon pump catheters; (I-R, II-R)
 - G. Percutaneous or surgical circulatory assist device; (I-R, II-recommended)
 - H. Thrombectomy aspiration catheters or mechanical thrombectomy device; and (I-R, II-R)
 - I. Embolic protection device; (I-R, II-R)
 7. There shall be documentation that all equipment is checked according to the hospital preventive maintenance schedule. (I-R, II-R)
- (D) The cardiac care unit of a designated STEMI center shall have the following personnel and equipment:

1. There shall be a designated medical director who meets the continuing educational requirements in these regulations; (I-R, II-R, III-R)
 2. A physician who is not the emergency department physician shall be on duty or available twenty-four (24) hours a day, seven (7) days a week; (I-R/IA, II-R/IA, III-R/IA)
 3. Registered nurses and other essential personnel on duty twenty-four (24) hours a day, seven (7) days a week: (I-R, II-R, III-R)
 4. Registered nurses shall have a minimum of eight (8) hours every year of cardiovascular continuing nursing education as determined appropriate by the STEMI center medical director and as appropriate to the practitioner's level of responsibility; (I-R, II-R)
 5. Registered nurses shall have a minimum of eight (8) hours every other year of cardiovascular continuing nursing education as determined appropriate by the STEMI center medical director and as appropriate to the practitioner's level of responsibility; (III-R)
 6. Registered nurses shall be credentialed yearly as determined by the hospital; (I-R, II-R, III-R)
 7. The cardiac care unit shall have written care protocols for identification and treatment of STEMI patients available to the cardiac unit personnel and should be reviewed annually and revised as needed; (I-R, II-R, III-R)
 8. Equipment for resuscitation and to support care for the STEMI patient including, but not limited to: (I-R, II-R, III-R)
 - A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes of all sizes, bag-mask resuscitator and sources of oxygen;
 - B. Suction devices;
 - C. Telemetry, electrocardiograph, cardiac monitor and defibrillator;
 - D. All standard intravenous fluids and administration devices and intravenous catheters; and
 - E. Drugs and supplies necessary for emergency care;
 9. There shall be documentation that all equipment is checked according to the hospital preventive maintenance schedule.
- (E) Radiological and diagnostic capabilities for STEMI center designation including a mechanism for timely interpretation to aid in patient management shall include:
1. Resuscitation equipment readily available in the radiology department; (I-R, II-R, III-R, IV-R)
 2. Adequate physician and nursing personnel available with monitoring equipment to fully support the STEMI patient and provide documentation of care during the time the patient is physically present in the radiology department and during transportation to and from the radiology department; (I-R, II-R, III-R, IV-R)
 3. There shall be X-ray capability with twenty-four (24) hours a day, seven (7) days a week coverage by technicians with a response time of twenty (20) minutes or less of notification; (I-R, II-R, III-R, IV-R)
 4. In-house computerized tomography; and (I-R, II-R)
 5. Computerized tomography technician. (I-R-IH, II-R-IH)
- (F) The operating room personnel, equipment and procedures shall include and not be limited to: (I-R, and II-R for those STEMI centers that shall provide cardiac thoracic surgery capability)
1. Operating room staff shall be available twenty-four (24) hours a day, seven (7) days a week;
 2. An on call heart team shall be promptly available;
 3. Equipment shall include, but not be limited to:
 - A. Thermal control equipment for patient and resuscitation fluids;
 - B. X-ray capability;
 - C. Instruments and equipment necessary for cardiothoracic surgical services;

- D. Monitoring equipment; and
- E. Resuscitation equipment readily available to the operating room;
- 4. There shall be documentation that all equipment is checked according to the hospital preventive maintenance schedule.
- (G) The hospital shall meet **post-anesthesia recovery room** (PAR) standards for STEMI center designation to include: (I-R and II-R—for those STEMI centers that shall provide cardiothoracic surgery capability)
 - 1. Registered nurses and other essential personnel who are not on duty shall be on call and available twenty four (24) hours a day, seven (7) days a week within sixty (60) minutes;
 - 2. Registered nurses shall maintain core competencies yearly as determined by the hospital;
 - 3. Equipment for resuscitation and to provide life support for the STEMI patient shall include, but not be limited to:
 - A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes of all sizes, bag-mask resuscitator, sources of oxygen and mechanical ventilator;
 - B. Suction devices;
 - C. Telemetry, electrocardiograph, cardiac monitor and defibrillator;
 - D. All standard intravenous fluids and administration devices, including intravenous catheters; and
 - E. Drugs and supplies necessary for emergency care;
 - 4. There shall be documentation that all equipment is checked according to the hospital preventive maintenance schedule.
- (H) The following **clinical laboratory services** shall be available twenty-four (24) hours a day, seven (7) days a week including a mechanism for timely interpretation to aid in patient management:
 - 1. Standard analyses of blood, urine and other body fluids; (I-R, II-R, III-R, IV-R)
 - 2. Blood typing and cross-matching; (I-R, II-R, III-R)
 - 3. Coagulation studies; (I-R, II-R, III-R, IV-R)
 - 4. Comprehensive blood bank or access to a community central blood bank and adequate hospital blood storage facilities; (I-R, II-R, III-R)
 - 5. Blood bank or access to a community central blood bank and adequate hospital blood storage facilities; (IV-R)
 - 6. Blood gases and pH determinations; (I-R, II-R, III-R, IV-R)
 - 7. Blood chemistries; and (I-R, II-R, III-R, IV-R)
 - 8. Written policy that the STEMI patient receives priority. (I-R, II-R, III-R, IV-R)
- (I) There shall be documentation of adequate **support services** in assisting the patient's family from the time of entry into the facility to the time of discharge or transfer. (I-R, II-R, III-R, IV-R)
- (J) The hospital shall have **cardiac rehabilitation** or a written network agreement for the provision of cardiac rehabilitation; (I-R, II-R, III-R)
 - 1. Level I and Level II STEMI centers shall have Phase I cardiac rehabilitation on site. (I-R, II-R)

(4) Standards for Hospital Performance Improvement, Patient Safety, Outreach, Public Education and Training Programs for STEMI Center Designation

- (A) There shall be an **ongoing performance improvement and patient safety program** designed to objectively and systematically monitor, review and evaluate the quality, timeliness and appropriateness of patient care, pursue opportunities to improve patient care and resolve identified problems; (I-R, II-R, III-R, IV-R)
 - 1. All STEMI centers shall collect, trend and electronically report to the department key data indicators as identified by department, including but not limited to: (I-R, II-R, III-R, IV-R)

- A. Any STEMI center that performs PCI shall report all PCI-related data as identified by the department, including but not limited to the time from first medical contact or pre-hospital ECG STEMI findings to hospital door to device or balloon time; (I-R, II-R, III-R)
- B. Thrombolytic administration time--the time from first medical contact or pre-hospital ECG STEMI diagnosis to hospital door to needle time; (I-R, II-R, III-R, IV-R)
- C. Percentage of STEMI patients presenting within the treatment window for PCI and/or thrombolytic; and (I-R, II-R, III-R, IV-R)
- D. Percentage of eligible STEMI patients treated with for PCI and/or thrombolytic; (I-R, II-R, III-R, IV-R)
2. A regular morbidity and mortality review, at least quarterly; (I-R, II-R, III-R, IV-R)
3. Regular reviews of the reports generated by the department from the Missouri STEMI registry; (I-R, II-R, III-R, IV-R)
4. Regular reviews of pre-hospital STEMI care including inter-facility transfers; (I-R, II-R, III-R, IV-R)
5. Participation in EMS regional system of STEMI care as established by the department; (I-R, II-R, III-R, IV-R)
6. STEMI patients remaining greater than forty-five (45) [vs. thirty (30)]¹ minutes at the referring hospital prior to transfer will be reviewed as a part of the performance improvement and patient safety program; (I-R, II-R, III-R, IV-R)
7. The receiving hospital shall provide and monitor timely feedback to the EMS providers and referring hospital, if involved. This feedback shall include, but not be limited to, diagnosis, treatment and disposition. It is recommended that the feedback be provided within seventy-two (72) hours of admission to the hospital; (I-R, II-R, III-R, IV-R) When EMS does not provide patient care data on patient arrival or in a timely fashion (recommended within three (3) hours of patient delivery), this time frame shall not apply; and
8. Review and monitor the core competencies of the physicians, practitioners and nurses. (I-R, II-R, III-R, IV-R)
- (B) A cardiology **clinical support program** shall be established that provides physicians in the outlying region with telephone access to a cardiologist twenty-four (24) hours a day, seven (7) days a week. (I-R, II-R)
- (C) A **public education program** shall be established to promote STEMI prevention and signs and symptoms awareness. (I-R, II-R, III-R, IV-R)
- (D) A **professional education outreach program** shall be established in the region and outlying areas to provide training and other supports to improve care of STEMI patients. (I-R, II-R, III-R)
- (E) A **training program** on caring for STEMI patients shall be established for professionals in the STEMI center.
 1. There shall be a hospital-approved procedure for training nurses and clinical staff to be credentialed in STEMI care. (I-R, II-R, III-R, IV-R)
 2. The STEMI center shall have a mechanism to assure that all nurses providing care to STEMI patients shall complete a minimum of required continuing education to become credentialed in STEMI care as stated in these regulations; and
 3. The content and format of any STEMI continuing education courses developed and offered by a hospital shall be developed with the oversight of the STEMI medical director. A copy of the course curriculum used shall be filed with the department.

¹ Performance measures developed by the AHA/ACC work group indicate this time should be 30 minutes. (Krumholtz H, 2008)

- (F) The hospital shall be actively involved in local and regional EMS systems by providing training and clinical educational resources. (I-R, II-R, III-R, IV-R)

(5) Standards for the Programs in STEMI Research for STEMI Center Designation

- (A) The hospital and its staff shall support an ongoing research program in STEMI as evidenced by any of the following: production of evidence based reviews of STEMI program's process and clinical outcomes; publications in peer reviewed journals; reports of findings presented at regional or national meetings; receipt of grants for study of STEMI care; or participation in multi-center studies; (I-R)
- (B) The hospital shall agree to cooperate and participate with the department in conducting epidemiological studies and individual case studies. (I-R, II-R, III-R, IV-R)

Bibliography (for review purposes only)

Krumholtz H, et al. (2008). ACC/AHA 2008 Performance Measures for Adults with ST-Elevation and Non ST-Elevation Myocardial Infarction. A Report of the American College of Cardiology/American Heart Association Task Force on Performance Measures. *Circulation* , 118, 1-53.